

Notice of Allowability

Application No.

10/776,022

Examiner

Laura C. Hill

Applicant(s)

NECOLA SHEHADA ET AL.

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to ____.
2. ☒ The allowed claim(s) is/are 1-4, 6-16 and 21-26.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date ____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Marc Brown on 1 March 2007.

Please change the title to:

Implanted Surgical Drain with Multiple Sensing Elements for Monitoring Internal Tissue Condition

In Claim 1, line 1

After "property of", please insert —at least one—

In Claim 1, line 6

Please delete ";" and replace with —, wherein the surgical drain is not configured to penetrate either the first or second tissues;—

In Claim 25, line 1

After "property of", please insert —at least one—

In Claim 25, line 8

Please delete ";" and replace with —, wherein the surgical drain is not configured to penetrate the tissue;—

Reasons for Allowance

Election/Restrictions

Claims 1-4, 6-16, and 21-26 are allowable. The restriction requirement of Species I (claims 21-22) and Species II (claims 23-24), as set forth in the Office action mailed on 30 November 2006, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 23-24, directed to non-elected species are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The following is an examiner's statement of reasons for allowance: the art of record alone or in combination fails to disclose or fairly suggest an implantable surgical drain configured to rest against the surface of the tissue and configured to not penetrate

Art Unit: 3761

the tissue including first and second sensing elements to sense a physiological property of a first and second tissue in different locations. The following is the closest prior art:

Benaron et al. (US 5,769,791) discloses surgical tool 30,210 with tip 40 passing through or around internal body tissue (column 10, lines 29-38) or alternatively resting on tissue 207 and not penetrating through ti (column 18, lines 14-15, figure 6) comprising first transmitting element 22, 241,242 provides a light control signal using optical fibers (column 9, lines 23-31, column 18, lines 15-18), first and second sensing elements 24, 245, 246 that receive signals corresponding to the detected light (column 18, lines 20-21, figure 6), performs a color analysis and ascertains the desired spectral characteristics of the detected light, and provides the spectral data to the signal processor 26 (column 9, lines 32-36) which in turn provides the type of tissue to display system 28 (column 9, lines 38-42). However, Benaron doesn't disclose a surgical drain.

Crowley (US 6,882,875) discloses an interventional device 10, 90 inserted into the body (column 3, lines 15-16) and positioned against tissue 92 (column 5, lines 1-2, figure 5A) comprising a first transmitter 20 on the inner surface of the body (column 3, lines 25-40, figure 1), sensors 16, 38a, 38b for providing a signal (column 3, lines 45-52, column 4, lines 16-20), processor and display 14 (column 3, lines 19-24) but no surgical drain or motivation to combine with surgical drains since all other surgical drains penetrate inside the tissue.

Mayevsky (US 5,916,171) discloses a device that simultaneously monitors NADH, CBF and other physiological properties using a bundle of optical fibers resting against the

Art Unit: 3761

surface of the tissue (column 4, lines 10-20, column 6, lines 52-53, columns 9-10, table 3) but no surgical drain.

Frank (US 3,769,497) discloses a biomedical device having a surgical drainage tubing 13 coming from a catheterized patient having transmitting switch 19 and sensing device 16 for transmitting and detecting energy (column 2, lines 7-38, figure 1). One would not be motivated to modify the sensing devices of Benaron, Crowley or Mayevsky listed above with the drain since Frank discloses a drain that *penetrates* the tissue.

Takezawa et al. (US 5,108,364) discloses catheter 1 that is *implanted into a body cavity* and thus penetrates the tissue (column 3, lines 55-65) having temperature sensor 10 that detects energy and embedded within the catheter (column 4, lines 9-15), processor and display (column 4, lines 9-10) and drainage holes 5 (column 3, lines 29-38, figure 1A), and a second sensor that can simultaneously measure temperature at a plurality of regions (column 4, lines 24-26).

Bedingham (US 5,421,328) discloses an arterial catheter 53 with oxygen sensor 69, carbon dioxide sensor 71, and pH sensor 73 affixed to a distal end of transmitting element/optical fibers 75,77,79 on an inner surface of the catheter (column 7, lines 46-51, column 8, lines 2-4 and figure 2). Thus the catheter is implanted and penetrates the tissue.

Sullivan et al. (US 4,497,324) discloses a urinary, interperitoneal, intercardial, respiratory or intervascular catheter penetrating the tissue (column 5, lines 7-11) having drainage lumen 20 (column 3, lines 31-39), temperature transducer/sensor 32 imbedded in the catheter wall to detect temperature and convert said temperature to an

Art Unit: 3761

electrical signal (column 3, lines 60-63), and a transmitting element/electrical lead 34 imbedded in the catheter wall (column 4, lines 19-20).

Yanda (US 4,413,633) discloses catheter tube 10 inserted into a urethra and thus penetrating the tissue that forms the urethra and connected to drainage tube 30 (column 2, lines 32-35 and lines 42-47), sensor 38 and transmitter on inner surface of the catheter (column 3, lines 18-39 and figure 2).

Pavoni et al. (US 5,906,584) discloses electrodes/sensors 5 on outer surface of catheter 3 but catheter is inserted within tissue, and a monitor/reading apparatus and a power supply/energy delivery transmitting element (column 4, line 36-column 5, line 8, figures 6-7). Also there is no drain disclosed.

Frazee (WO 92/11803) discloses cardiopulmonary monitoring system 100 that transmits and receives optical signals to and from the interior of the *penetrated* blood vessel via fiber optic catheter 10, monitor/display, and processing (see abstract, etc).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (hours vary).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone

Art Unit: 3761

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura C. Hill
Examiner
Art Unit 3761
LCH

LCH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

TZalukaeva